Supreme Court, U.S.
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93-220 No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

DUPHAR, B.V.,

Petitioner,

—against—

KATHY D. TOBIN,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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August 11, 1993

73 pp

QUESTION PRESENTED

May a federal court, exercising diversity jurisdiction, assert personal jurisdiction over an alien defendant based solely on a stream of commerce theory plus the defendant's *national* contacts with the United States, when there is no evidence that the defendant has any contacts with the forum State?

BEST AVA

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Petitioner Solvay Duphar, B.V. ("Duphar"),[1] formerly known as Duphar, B.V., respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Sixth Circuit, entered on April 16, 1993, which reversed an order of the District Court for the Western District of Kentucky, entered on February 8, 1991, dismissing the complaint against Duphar for lack of personal jurisdiction.

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[1] In compliance with Supreme Court Rule 29.1, Duphar states that it is a wholly-owned subsidiary of Sovlay, S.A., a Belgian corporation.

In compliance with Supreme Court Rule 14.1(b) Duphar states that, in addition to itself and Tobin, Astra Pharmaceutical Products, Inc. ("Astra") is a party in this action.

OPINIONS BELOW

The Memorandum Opinion and Order of the District Court granting Duphar's motion to dismiss for lack of personal jurisdiction is reprinted at *Appendix A*. The Judgment of the District Court dismissing plaintiff's complaint against Duphar is reprinted at *Appendix B*.

The Judgment of the District Court for the plaintiff against Astra is reprinted at *Appendix C*. The Final Judgment of the District Court is reprinted at *Appendix D*.

The Opinion of the Court of Appeals reversing the District Court's order is published at 993 F.2d 528 and reprinted at *Appendix E*. The Judgment of the Court of Appeals reversing the District Court's order is reprinted at *Appendix F*. The Order of the Court of Appeals denying Astra's petition for rehearing is reprinted at *Appendix G*.[2]

JURISDICTION

The Judgment of the Court of Appeals was entered on April 16, 1993. The Order of the Court of Appeals denying Astra's petition for rehearing was entered on May 13, 1993. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

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[2] The opinions, orders and judgments below are reprinted in Appendices A through G. "A", "B", "C", ... "G" page references are to those Appendices.

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The constitutional and statutory provisions involved are:

The Due Process Clause of the Fourteenth Amendment to the United States Constitution;

The federal diversity statute, 28 U.S.C. § 1332;

The federal diversity removal statute, 28 U.S.C. § 1441; and

The Kentucky long-arm statute, Ky. Rev. Stat. Ann. § 454.210(2)(a).

These provisions are set forth at *Appendix H.*

STATEMENT OF THE CASE

In January 1987, Kathy D. Tobin was hospitalized for management of preterm labor. Her doctors prescribed ritodrine hydrochloride ("ritodrine") to avoid premature birth of Tobin's fetal twins. On March 17, Tobin's doctors discontinued her use of ritodrine. That afternoon, Tobin gave birth to healthy twins having a gestational age of 37 weeks. *See Tobin* v. *Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993) (*reprinted at Appendix E*).

On March 21, Tobin was hospitalized for treatment of congestive heart failure, cardiomyopathy, and pulmonary edema. Tobin underwent treatment culminating in a heart transplant on April 16, 1987. *See Id.* at E2-E3.

Tobin filed suit in Kentucky state court asserting product liability claims under state law against Astra Pharmaceutical Products, Inc. ("Astra"), the United States distributor of ritodrine, and Duphar, the Netherlands manufacturer of ritodrine. The suit was removed to the United States District

Court for the Western District of Kentucky on diversity grounds pursuant to 28 U.S.C. § 1441. The District Court granted Duphar's motion to dismiss for lack of personal jurisdiction. *See Id.* at E1.

Tobin proceeded against Astra. After trial, the jury awarded Tobin $4.5 million, finding Astra liable on theories of defective design and failure to warn. *See Id.* at E3.

The District Court denied Astra's motion for judgment notwithstanding the verdict or, in the alternative, for a new trial. Astra appealed. Tobin appealed the dismissal of Duphar.

The Sixth Circuit affirmed the judgment against Astra and reversed the District Court's dismissal of Duphar, concluding that Duphar "purposefully availed itself of the United States market" and, therefore, was subject to the jurisdiction of Kentucky state courts. *See Id.* at E1.

The court found that Kentucky courts had interpreted Kentucky's long-arm statute, Ky. Rev. Stat. Ann. § 454.210(2)(a), to confer jurisdiction to the limits of the Due Process Clause of the Fourteenth Amendment. *See Id.* at E22. The court then proceeded to inquire whether the requisite criteria for personal jurisdiction were met. The criteria applied by the court were the following:

> First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

See Id. at E23 (citing *Theunissen* v. *Matthews*, 935 F.2d 1454, 1460 (6th Cir. 1991) (citing *Southern Machine Co.* v. *Mohasco Indus.*, 401 F.2d 374, 381 (6th Cir. 1968))).

In finding that the first criterion—purposeful availment—was met, the Sixth Circuit relied on the following facts:

> 1. Duphar "submitted a New Drug Application to the [Food and Drug Administration]" and "conducted clinical studies in the United States" and
>
> 2. Duphar "sought out a United States distributor to exploit the United States market"

See Id. at E23. The court also noted that these "contacts" would be sufficient "[e]ven under the test set forth in the plurality opinion of *Asahi*, relied on by both Duphar and the district court." *See Id.* at E24. The court wrote that "Duphar has contact that is 'something more' than mere awareness that the stream of commerce will sweep the product into the forum state." *See Id.* (citing *Asahi Metal Industry Co.* v. *Superior Court*, 480 U.S. 102, 111-12 (1987)). The court went on to argue that by entering into a national distribution agreement encompassing the United States generally, Duphar had effectively appointed Astra "'to serve as the sales agent in the forum State [Kentucky]'" Consequently, the court concluded, Duphar "purposefully availed" itself of what "[e]ven the *Asahi* plurality recognized" could "'indicate an intent or purpose to serve the market in the forum State.'" *See Id.* at E24-E25 (quoting *Asahi*, 480 U.S. at 112).

Nowhere in its opinion did the court rely on any act or alleged act by the defendant Duphar within Kentucky or specifically directed towards Kentucky, as opposed to the

United States as a whole. The court considered and summarily rejected, Duphar's argument that the Due Process Clause limitations on the exercise of *in personam* jurisdiction required that the defendant "purposefully avail itself of the Kentucky market as distinguished from any other state in the union." *See Id.* at E26.

Similarly, nowhere in its opinion did the court rely on any act or alleged act by Duphar's distributor, Astra, within Kentucky or specifically directed towards Kentucky. The Sixth Circuit cited no evidence that Astra ever was present in Kentucky, performed any act in Kentucky, or performed any act specifically directed towards Kentucky. The sole connection between Astra and Kentucky relied on by the Sixth Circuit (and supported by the record) was Astra's contractual authority to market ritodrine in the United States as a whole, including Kentucky.

With respect to the second criterion—that the cause of action arise from the defendant's activities in the forum State—the Sixth Circuit found that the "cause of action arose from defendant's activities in causing ritodrine to be sold in Kentucky." *See Id.* at E26. The court did not enumerate these "activities." Presumably, they consisted of the same two facts relied on to find the first criterion satisfied: (1) submission of an application and supporting data to the Food and Drug Administration ("FDA") and (2) the existence of an agreement with a distributor to distribute in the United States.

The court offered no explanation, however, of how these activities "gave rise" to Tobin's cause of action.[3] *See Id.* at E26.

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[3] The court also found that the third criterion--"fairness"--was satisfied. *See Id.* at C27-C28.

REASONS FOR GRANTING THE WRIT

I. THE SIXTH CIRCUIT'S DECISION VIOLATES DUE PROCESS LIMITATIONS ON PERSONAL JURISDICTION

The Sixth Circuit's decision contains no reference to *any* contact by Duphar with the forum state, Kentucky. Given the complete absence of any contacts by Duphar with the forum state, the Sixth Circuit's decision violates due process limitations on *in personam* jurisdiction.

Apparently unable to identify any contacts by Duphar with the forum state, the Sixth Circuit relied on "contacts" by Duphar with the United States. These "contacts" consisted of nothing more than the following:

> 1. the foreign corporation "submitted a New Drug Application to the [Food and Drug Administration]" and "conducted clinical studies in the United States" and
>
> 2. the foreign corporation "sought out a United States distributor to exploit the United States market."

See Tobin v. *Astra*, *Appendix E* at E23.

In relying on those "contacts," the Sixth Circuit transformed the requirement of "purposeful availment of

contacts with the forum state" into a "national contacts" test. *See Appendix E* at E1, E23-E27.

Although the quantity and quality of the contacts has changed over time, this Court has always required that the defendant's contacts be with the forum State, not the United States as a whole. *See International Shoe* v. *Washington*, 326 U.S. 310 (1945) ("due process requires only that in order to subject a defendant to a judgment *in personam*, if he be not present within the territory of the forum, he have certain minimum contacts ***with it*** such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice'") (emphasis added, citations omitted); *Pennoyer* v. *Neff*, 95 U.S. 714, 733 (1878) (due process requires defendant's presence within the territory of ***the state*** for personal jurisdiction).

This Court's decisions have uniformly held that an exercise of jurisdiction over a nonresident defendant comports with due process only if the defendant purposefully avails itself of contacts ***with the forum State***. *See Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462, 474 (1985) (a state may exercise jurisdiction consistent with due process where "the defendant purposefully established 'minimum contacts' ***in the forum State***") (emphasis added); *Helicopteros Nacionales de Colombia, S.A.* v. *Hall*, 466 U.S. 408, 414 (1984) ("due process is not offended by a State's subjecting the corporation to its *in personam* jurisdiction when there are sufficient contacts between ***the State*** and the foreign corporation") (emphasis added); *World-Wide Volkswagen Corp.* v. *Woodson*, 444 U.S. 286, 291 (1979) ("a state court may exercise personal jurisdiction over a nonresident defendant only so long as there exist 'minimum contacts' between the defendant ***and the forum state***") (emphasis added, citations omitted); *Shaffer* v. *Heitner*, 433 U.S. 186, 207 (1976) (a state court may exercise jurisdiction over a nonresident defendant only where there exist minimum contacts "among

the forum State, the defendant, and the litigation") (emphasis added).

This Court, in *Asahi*, reiterated the requirement that the defendant's contacts be with the forum State. *Asahi*, 480 U.S. at 102, 108-9 ("'[T]he constitutional touchstone . . . remains whether the defendant purposefully established "minimum contacts" ***in the forum State***.'") (emphasis added). In posing examples of additional conduct beyond placing a product into the stream of commerce sufficient to subject a foreign defendant to personal jurisdiction, this Court was careful to indicate that the additional conduct must be "purposefully directed toward ***the forum State***." *Asahi*, 480 U.S. at 112 (emphasis added). Specifically, the Court wrote, "Additional conduct of the defendant may indicate an intent or purpose to serve the market ***in the forum State***, for example, designing the product for the market ***in the forum State***, advertising ***in the forum State***, establishing channels for providing regular advice to customers ***in the forum State***, or marketing the product through a distributor who has agreed to serve as the sales agent ***in the forum State***." *Id.* (emphasis added).

In evaluating whether the defendant Asahi had met this additional requirement, this Court did not inquire into Asahi's contacts with the *United States*. Rather, this Court inquired into Asahi's contacts with California. *Asahi*, 480 U.S. at 112-113 ("[R]espondents have not demonstrated any action by Asahi to purposefully avail itself of ***the California market***. Asahi does not do business ***in California***. It has no office, agents, employees, or property ***in California***. It does not advertise or otherwise solicit business ***in California***. It did not create, control, or employ the distribution system that brought its valves to ***California***. There is no evidence that Asahi designed its product in anticipation of sales ***in California***." (emphasis added) (citations omitted)).

By contrast, the Sixth Circuit relied on no activity of the defendant within Kentucky or specifically directed[4] to Kentucky. Instead, the Sixth Circuit relied on Duphar's submission of an application to the FDA and its entry into an agreement authorizing Astra to distribute ritodrine throughout the United States. *See Tobin* v. *Astra*, *Appendix E* at E23.

These two "national contacts" do not satisfy the "constitutional touchstone" of due process limitations on personal jurisdiction because they did not occur within, nor were they directed towards, the forum State. Absent congressional authorization, national contacts will not satisfy the requirement that a defendant purposefully avail itself of the forum State. The Court in *Asahi* explicitly noted that an inquiry into contacts with the forum state was distinct from —and more rigorous than—an inquiry into contacts with the United States as a whole. *Asahi*, 480 U.S. at 113 n.* ("We have no occasion here to determine whether Congress could, consistent with the Due Process Clause of the Fifth Amendment, authorize federal court personal jurisdiction over alien defendants based on the aggregate of *national* contacts, rather than on the contacts between the defendant and the State in which the federal court sits." (emphasis in original)).

The Sixth Circuit's decision thus transforms the requirement of minimum contacts with the forum state into a national contacts test, contrary to the consistent teachings of this Court. As such, the decision raises serious questions of federalism. This Court has long recognized that due process limitations on personal jurisdiction reflect "territorial limitations on the power of the respective states," not merely

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[4] While this Court has held that the *conduct* causing the contact with the forum State need not occur within the state, the contacts with the forum State must "proximately result" from the defendant's out-of-state conduct. *Burger King*, 471 U.S. at 475.

considerations of fairness. *Hanson* v. *Denckla*, 357 U.S. 235, 251 (1958) (limitations on state jurisdiction "are more than a guarantee of immunity from inconvenient or distant litigation. They are a consequence of territorial limitations on the power of the respective States").

Moreover, in this regard there is no principled distinction to be drawn between an alien defendant and a nonalien defendant lacking contacts with the forum State. If a "national contacts" test is sufficient to permit assertion of jurisdiction over a foreign defendant, it should be sufficient to confer jurisdiction over a U.S. defendant as well, *e.g.*, a local manufacturer whose products are purchased and distributed by a national retailer. Such a result, however, is directly contrary to the regime of *International Shoe* and the principles of federalism to which it is meant to give effect.

CONCLUSION

For the foregoing reasons, a writ of certiorari should issue to the United States Court of Appeals for the Sixth Circuit.

Respectfully submitted,

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August 11, 1993

APPENDIX A

Memorandum and Order of the District Court
Entered February 8, 1991

United States District Court
Western District of Kentucky
At Louisville

Civil Action No. 88-0350-L(CS)

KATHY D. TOBIN, *Plaintiff,*

v.

DUPHAR B.V. and
ASTRA PHARMACEUTICAL PRODUCTS, INC.
PRODUCTS, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

This case stands submitted on motion by the defendant, Duphar B.V., for dismissal, on the grounds that this court lacks personal jurisdiction. The court has considered the materials tendered in support of and in opposition to the motion, and for the reasons set forth herein, determines that the motion to dismiss should be granted.

I.

This is a products liability case. Plaintiff, Kathy Tobin, a Kentucky resident, allegedly suffered injury to her heart caused by taking a drug to prevent premature labor during her pregnancy.

Her heart was severely damaged, and she underwent a heart transplant. Defendant, Astra Pharmaceutical Products, Inc., sells the drug, ritodrine hydrochloride, in this country under the tradename Yutopar. Defendant, Duphar B.V., a Dutch company, developed and manufactures Yutopar, and licensed Astra to sell Yutopar in the United States.

There is no corporate affiliation between Duphar and Astra. Their only relationship is that created by a Trademark License Agreement and a Supply Agreement into which they entered. Under those non-exclusive agreements, Duphar supplies Astra with such quantities of Yutopar as Astra requires for the processing, distribution, and/or sale of Yutopar in the United States, its territories and possessions, and Puerto Rico. There is no evidence that Duphar plays any active role in, exercises control over, or in any way influences Astra's marketing and distribution decisions or tactics.

Duphar's only presence in this country is its ownership interest in five corporations, none of which are located in, or do business in, Kentucky. Duphar's activities in this country with respect to Yutopar stem solely from Duphar's submission in 1979 of a New Drug Application to the United States Food and Drug Administration, seeking FDA approval for Yutopar's use in the United States. In order to satisfy the FDA's new-drug approval requirements, Duphar subjected Yutopar to clinical trials in the United States. The FDA clinical tests were coordinated by Dr. John Peter, an employee of Duphar B.V., and were conducted in cooperation with Midwest Medical Research, Inc., a Columbus, Ohio corporation.[6] Yutopar was approved for use in the United

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[6] At some point, Duphar purchased Midwest Medical Research, Inc. and named it Duphar Laboratories, Inc. Subsequently, it was renamed Kali-Duphar Laboratories, Inc., which remained headquarters in Columbus Ohio until it merged into Reid-Rowell of Marietta, Georgia of the United States Corporations in which Duphar holds an interest, only that which has now that [sic] merged into Reid-Rowell was involved in activities concerning Yutopar.

States in 1980, and since then has been marketed and distributed here by Duphar licensees.

II.

Whether this court has personal jurisdiction over Duphar is governed by the law of Kentucky. *Poyner* v. *Erma Werke GMBH*, 618 F.2d 1186, 1187 (6th Cir. 1980). Under Kentucky's long-arm statute,

> A court may exercise personal jurisdiction over a person who directly or by an agent, as to a claim arising from the person's:
>
> (1) Transacting any business in this Commonwealth;
>
> (2) Contracting to supply services or goods in this Commonwealth;
>
> (3) Causing tortious injury by act or omission in this Commonwealth;
>
> (4) Causing tortious injury in this Commonwealth by an act or omission outside this Commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth; . . .
>
> (5) Causing injury in this Commonwealth to any person by breach of warranty expressly or impliedly made in the sale outside this Commonwealth where the seller knew such person would use, consume, or be affected by the goods in this commonwealth, if he also regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed . . . in this Commonwealth.

KRS 454.201(2)(a).

In count I of her complaint, plaintiff alleges that Duphar was negligent in the design, testing, and manufacture of Yutopar, and negligently failed to include adequate instructions and warnings for its use. In count III, plaintiff claims that Duphar and Astra breached express and implied warranties allegedly made to plaintiff. In count IV, plaintiff alleges Duphar and Astra are strictly liable for having distributed a product in a defective condition unreasonably dangerous to consumers. These allegations establish that all of the acts which form the basis for Duphar's liability are related to design, testing, manufacture and sale of Yutopar. There is no allegation or evidence that any of these acts took place in Kentucky, so subsections 4 and 5 of KKS 454.210(2)(a) are the only basis for long-arm jurisdiction over Duphar.

These two subsections of Kentucky's long-arm statute have been construed to extend personal jurisdiction to foreign corporations that have so-called "minimum contacts" with Kentucky. *Poyner* v. *Erma Werke GMBH*, 618 F.2d 1186, 1189 (6th Cir. 1980). Nevertheless, a defendant's conduct or the consequences a defendant causes must have such a substantial connection with Kentucky to make the exercise of jurisdiction over the defendant "reasonable." *Southern Machine Co.* v. *Mohasco Industries, Inc.*, 401 F.2d 374, 381 (6th Cir. 1968). Moreover, for a defendant to come with this court's jurisdiction, the cause of action must arise from the defendant's activities in Kentucky. *Id.* In sum, this court's jurisdiction, and the "outer limits of due process," extend only to those who have purposely availed themselves of the privilege of acting or causing a consequence in this state. *Id.*

The United States Supreme Court has elaborated on how a defendant can purposefully avail itself of the privilege of conducting activities in a forum state, and thus, how far the "outer limits of due process" extend. In *Asahi Metal Ind.* v. *Super. Ct. of Cal., Solano Cty.*, 480 U.S. 102, 107 S.Ct., 1026, 94 L. Ed. 2d 92 (1987), the Court considered the question of when an alien corporation is properly subject to a state court's personal jurisdiction for injuries suffered as a result of a product manufactured by the alien corporation. The plurality opinion in

Asahi held that merely placing a product into the stream of commerce, even with awareness that it may reach the forum state, does not establish the sufficient minimum contacts with the forum state to support the forum-state court's exercise of personal jurisdiction over the manufacturer. Instead, according to the plurality opinion, the manufacturer must engage in some "additional conduct," beyond placing the product into the stream of commerce, to establish that its actions are purposefully directed toward the forum state. 107 S.Ct. at 1032. The plurality opinion suggests that such additional conduct could be acts that "indicate an intent to serve the market in the forum state," as by designing the product for the forum-state market, advertising in the forum state, establishing channels for providing regular advice to customers in the forum state, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum state. *Id.*

III.

We conclude that for purposes of this action, Duphar lacks sufficient "minimum contacts" with Kentucky to subject it to this court's personal jurisdiction, because Duphar has not been shown to have purposefully availed itself of the privilege of doing business here, either itself or through an agent. Merely because Astra has the right to distribute Yutopar in Kentucky does not make Astra Duphar's agent in Kentucky. *See, e.g., R.L. Lipton Distributing* v. *Driveck Importers, Inc.*, 811 F.2d 967, 970 (6th Cir. 1987) (even exclusive distributor was independent contractor; no personal jurisdiction over supplier whose product the independent contractor distributed). Nothing among the acts on which plaintiff relies establishes that Duphar itself ever engaged in the sort of "additional conduct," as contemplated by the *Asahi* plurality, as could be considered purposely directed at Kentucky. Duphar does not do business in Kentucky. It has no office, agents, employees, or property in Kentucky. It does not advertise or otherwise solicit business in Kentucky. It did not create or control Astra, the entity whose activities resulted in distribution of Yutopar in Kentucky. There is no evidence that Duphar designed its product in

anticipation of sales in Kentucky. The most that can be said is that Duphar employed Astra as its means of distributing Yutopar nationwide, but there is no evidence that Duphar played any role in how that distribution scheme was to be implemented, or that Kentucky was in any way singled out by Duphar or Astra. Plaintiff argues that by licensing Astra to distribute Yutopar, Duphar has placed Yutopar into the stream of commerce throughout the United States, including Kentucky, and that Duphar earns revenues in the United States, through its sales of Yutopar to Astra, which in turn sells the product in all fifty states, including Kentucky. However, given the broad sweep and expansive scope of the Duphar-Astra agreements, they do no more than create awareness on the part of Duphar that its product may end up being used in Kentucky. That knowledge "does not convert the mere act of placing the product into the stream [of commerce] into an act purposefully directed toward the forum State." *Asahi*, 107 S. Ct. at 1032.

In opposition to the motion to dismiss, besides Duphar's involvement with Astra, plaintiff points to Duphar's FDA new-drug application and to the clinical studies it conducted under the auspices of what later became Duphar Laboratories. Plaintiff also cites the fact that in connection with his efforts to have Yutopar approved by the FDA, and to obtain a licensing arrangement with a licensee here, Duphar's employee, Dr. Peter, traveled to the United States and lived for a time in Columbus, Ohio. However, the activities of Dr. Peter had no particular connection with Kentucky. None of the license agreements Dr. Peter sought involved Kentucky companies, nor was any agreement negotiated or consummated in Kentucky. None of the clinical trials were conducted here and there is no suggestion that Kentucky residents were involved in any way. The mere fact that FDA trials and, ultimately FDA approval, would enable the drug to be sold in Kentucky is not activity directed toward Kentucky, anymore than is placing Yutopar into a stream of commerce that would ultimately flow here.

Prior to *Asahi*, it may have been the law in this circuit that merely placing a product into the stream of commerce, with knowledge that the product would be used in Kentucky, would be

sufficient to subject the defendant to personal jurisdiction of Kentucky's courts. *Payner* v. *Erma Werke GMBH*, *supra*. However, the plurality opinion in *Asahi* rejects the "stream of commerce" test. Plaintiff argues that because only a plurality of the Supreme Court joined in that holding, *Asahi* is not persuasive. However, we do not feel free to ignore the reasoning of the *Asahi* plurality. In fact, that reasoning comports with the Kentucky long-arm statute's requirements that the non-resident defendant's contacts must involve "regularly" doing or soliciting business, a "persistent course of conduct," or generation of "substantial revenue" in Kentucky. The legislature, in defining what acts confer personal jurisdiction, expressed an intent to require that a defendant do more than simply place a product into the stream of commerce, thereby enabling it to be used in Kentucky. Without some "additional conduct" showing Duphar's intent to serve the market in Kentucky in particular, or which establishes that Duphar initiated some regular, persistent or substantial connection with this state, Duphar is not subject to the personal jurisdiction of this court. The motion to dismiss is therefore GRANTED.

A separate judgment will be entered in accordance with this order and opinion.

IT IS SO ORDERED this 8th day of February, 1991.

/s/ CHARLES R. SIMPSON III
UNITED STATES DISTRICT JUDGE

APPENDIX B

Judgment of the District Court
Entered February 8, 1991

United States District Court
Western District of Kentucky
At Louisville

Civil Action No. 88-0350-L(CS)

KATHY D. TOBIN, *Plaintiff,*

v.

DUPHAR B.V. and
ASTRA PHARMACEUTICAL PRODUCTS, INC.
PRODUCTS, INC.,

Defendants.

JUDGMENT

For the reasons set forth in the memorandum opinion entered herewith, and the court being fully advised, plaintiff's complaint against Duphar B.V. is hereby DISMISSED WITHOUT PREJUDICE.

IT IS SO ORDERED this 8th day of February, 1991.

/s/ CHARLES R. SIMPSON III
UNITED STATES DISTRICT JUDGE

APPENDIX C

Judgment of the District Court
Entered March 12, 1991

United States District Court
Western District of Kentucky
At Louisville

Civil Action No. 88-0350-L(CS)

KATHY D. TOBIN, *Plaintiff,*

v.

DUPHAR B.V. and
ASTRA PHARMACEUTICAL PRODUCTS, INC.
PRODUCTS, INC.,

Defendants.

This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdicts.

IT IS ORDERED AND ADJUDGED:

That the plaintiff, Kathy D. Tobin, recover of the defendant, Astra Pharmaceuticals, Inc., the sum of $4,508,399.87, together with interest thereon at the rate of 6.21% per annum until paid, and her recoverable costs.

/s/ JESSE W. GRIDER
CLERK

/s/ M. W. LUPIS
DEPUTY CLERK

APPENDIX D

Order to Enter Final Judgment of the District Court Entered March 12, 1991

United States District Court
Western District of Kentucky
At Louisville

Civil Action No. 88-0350-L(CS)

KATHY D. TOBIN, *Plaintiff*,

v.

DUPHAR B.V. and
ASTRA PHARMACEUTICAL PRODUCTS, INC.
PRODUCTS, INC.,

Defendants.

To The Clerk:

Enter final judgment in the above-entitled case, there being no just reason for delay. Form of judgment approved.

/s/ CHARLES R. SIMPSON III
UNITED STATES DISTRICT JUDGE

APPENDIX E

Opinion of the Court of Appeals
Entered April 16, 1993

Nos. 91-6413/6478

United States Court of Appeals

For the Sixth Circuit

KATHY D. TOBIN,
Plaintiff-Appellee (91-6413),
Plaintiff-Appellant (91-6478),

v.

ASTRA PHARMACEUTICAL
PRODUCTS, INC.,
Defendants-Appellant (91-6413),

DUPHAR, B.V.,
Defendant-Appellee (91-6478).

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY

Decided and Filed April 16, 1993

RALPH B. GUY, JR., Circuit Judge

Before: GUY and RYAN, Circuit Judges; and CHURCHILL, Senior District Judge.*

RALPH B. GUY, JR., Circuit Judge. Defendant Astra Pharmaceutical Products, Inc., appeals the denial of its motion for judgment notwithstanding the verdict, or in the alternative for a new trial, in this diversity products liability action. On appeal, Astra argues that its motion for a j.n.o.v. should have been granted, because the causation hypothesis of plaintiff's expert does not have a generally accepted scientific basis and the risk/benefit theory and failure to warn theory proposed by the plaintiff cannot establish liability under Kentucky law. Astra also argues that its motion for a new trial should have been granted for two reasons: first, because two of the plaintiff's experts either expressed opinions not disclosed prior to trial or relied on more reports than were disclosed and, second, because the verdict was against the clear weight of the evidence. We reject defendant's arguments and affirm.

Plaintiff appeals the dismissal of defendant Duphar B.V., the manufacturer of the drug at issue based in the Netherlands, for lack of personal jurisdiction. We find dismissal was inappropriate because Duphar B.V. purposefully availed itself of the United States market.

I.

In 1986, Kathy Tobin was 19 years old and pregnant with twins. Her expected date of delivery was in early April 1987. Other than a mitral valve prolapse, or heart murmur,[1] a rather common finding in reproductive-age women, Tobin was a healthy young woman. In mid-October 1986, Tobin was hospitalized for dehydration. She was having difficulty keeping down food and fluids and required hydration. Her condition was diagnosed as viral in origin. She was released after a few days and her pregnancy

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* Honorable James P. Churchill, United States District Court for the Eastern District of Michigan, sitting by designation.

[1] Patients with this condition have an excess of tissue area such that, when the ventricle narrows, the flaps of the mitral valve are pulled back into the left atrium.

progressed. In January 1987, Tobin was admitted to the hospital for management of preterm labor. She was given an injection of magnesium sulphate and then was placed on an oral maintenance does of ritodrine.[2] Dosage levels varied, being increased when contractions returned.

Tobin testified that after each dose of ritodrine her pulse would race and her heart felt as "it is was going to jump out of my skin"; her face would also flush and her hands and legs would swell. She was advised that these symptoms were normal side effects of ritodrine. On March 9, 1987, Tobin's obstetricians reduced the dosage because of her rapid heart rate. On March 16, 1987, Tobin informed her doctors that she could not breathe when lying down, and she was told to further reduce the ritodrine dosage. At 1:30 a.m. on March 17, she was admitted to the hospital with symptoms of tachypnea (rapid breathing), dyspnea (shortness of breath), and a gallop rhythm of the heart. At this time, it also was noted that Tobin had a grade I/IV systolic murmur of the heart. X-rays revealed that she had pulmonary edema (fluid in the lungs) and cardiomegaly (enlargement of the heart) caused by congestive heart failure. An electrocardiogram revealed advanced dilated cardiomyopathy.[3] Ritodrine was discontinued, and that afternoon plaintiff delivered healthy twins having a gestational age of 37 weeks.

On March 20, Tobin was discharged from the hospital with instructions to follow up with a cardiologist. The next day she was readmitted for treatment of congestive heart failure, cardiomyopathy, and pulmonary edema. After five days in the hospital, she was again released. She was readmitted on April 10, and on April 15 a mechanical heart, or ventricular assist device, was inserted until a donated heart for a heart transplant could be found. On April 16, Tobin underwent a heart transplant.

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[2] Ritodrine hydrochloride is marketed under the trade name Yutopar.

[3] Dr. Waller testified that there are three types of cardiomyopathies based upon the size of the ventricle. In the dilated forms, the ventricles are stretched out and do not contract well.

Plaintiff filed suit against Duphar, B.V., the corporation in the Netherlands that manufactures ritodrine, and against Astra Pharmaceutical, Duphar's United States distributor. After removal to federal court on diversity grounds, the district court granted Duphar's motion to dismiss for lack of personal jurisdiction. Plaintiff proceeded against Astra. After a two-week trial, the jury returned a verdict in favor of the plaintiff. The jury awarded Tobin approximately $4.5 million, finding Astra liable on the basis of defective design and failure to warn for the conditions that led to her heart transplant. The district court denied Astra's motion for judgment notwithstanding the verdict or in the alternative for a new trial, and Astra timely appealed.

II.

Plaintiff cannot prevail under any theory if ritodrine did not substantially contribute to her heart disease. In other words, plaintiff must prove causation. Astra attacks the testimony of plaintiff's causation expert, Dr. Waller, as based on nothing but opinion and not founded on a generally accepted scientific basis. Plaintiff refutes this claim by pointing not only to Dr. Waller's credentials,[4] but also to various studies conducted; Astra's own package inserts; and the testimony of Astra's causation expert, Dr. O'Connell.

Ritodrine belongs to a class of compounds known as betamimetics. These compounds mimic adrenaline, a natural

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[4] Dr. Waller is board certified in internal medicine and board certified in cardiology with subspecialties in anatomic pathology and cardiovascular pathology. At the time of trial, he was a professor of pathology and medicine at Indiana University. He interned at the Mayo Clinic and Mayo Graduate School of Medicine and then earned a master's degree in medicine and pathology at the University of Minnesota. He is the director of Indiana University's Section of Cardiovascular Pathology Registry and has been a member of the editorial board of the Journal of the American College of Cardiology and the International Journal of Cardiology. Dr. Waller has also been a review board consultant for 12 other authoritative medical journals in the cardiovascular field and has been the editor of major medical texts. Dr. Waller has published over 250 articles, studies, and treatises.

hormone. A betamimetic, or beta-receptor agonist, exerts its effect by stimulating beta-adrenergic receptors. There are at least two sub-groups of beta receptors, beta-1 and beta-2. The heart contains beta-1 receptors, which, when stimulated, result in an increased heart rate and a rise in systolic pressure concomitant with a decrease in diastolic pressure. The force with which the heart contracts also increases. Stimulation of beta-2 receptors inhibits contractility of smooth muscle, such as that contained in the uterus.

Ritodrine, which at low doses preferentially affects beta-2 receptors, is administered to pregnant women to arrest premature labor. The drug, however, may also exert pronounced beta-1 effects. Ritodrine may unmask occult heart conditions and is specifically contraindicated when a patient suffers from cardiac disease.

Both plaintiff's causation expert, Dr. Waller, and defendant's causation expert, Dr. O'Connell, testified that Tobin's viral infection in October 1986 resulted in myocarditis, an inflammation of the heart muscle. Dr. O'Connell testified that approximately 70 percent of us have been infected by a virus that causes myocarditis and that at least 50 percent of us have actually had the virus infect our heart, and therefore, by definition, have had myocarditis. But Dr. O'Connell testified that most people recover without ever having known it. Dr. Waller's main causation theory was that Tobin would have recovered from the myocarditis, just like the vast majority of people, if it had not been for the added strain of the ritodrine. Dr. O'Connell, on the other hand, testified that plaintiff's cardiomyopathy could be explained by the myocarditis and her twin pregnancy which placed additional strain on her heart. Dr. Waller also felt that there was evidence that ritodrine had a direct effect on plaintiff's heart.

Pursuant to Federal Rule of Evidence 702, this circuit has adopted a four-part test for the admission of expert testimony: "(1) a qualified expert (2) testifying on a proper subject (3) which is in conformity to a generally accepted explanatory theory (4) the probative value of which outweighs it prejudicial effect." *Sterling* v. *Velsicol Chem. Corp.*, 855 F.2d 1188, 1208 (6th Cir. 1988). It

is the third criteria [*sic*] which Astra claims was not met.[5] Defendant argues vigorously before this court that Dr. Waller's testimony was "junk science," a term made popular by Peter Huber in his recent work *Galileo's Revenge: Junk Science in the Courtroom* (1991), and that Dr. Waller's causation theory does not withstand the "hard look" approach we have adopted in dealing with expert testimony on scientific matters. *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1352 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992). Defendant argues that Dr. Waller did not subject the view he expressed at trial to peer review, that he presented no epidemiological evidence, and that the treating physicians did not attribute Tobin's condition to the ritodrine therapy. As for the last claim, Tobin's treating doctors stated that they were not concerned with diagnosing what had caused plaintiff's heart to fail, but only with keeping her alive. Defendant's other complaints ignore the evidence.

While Dr. Waller did not publish any article regarding the view that ritodrine aggravated Kathy Tobin's myocarditis, and thus was a substantial cause of her cardiomyopathy, he did rely on several sources already published. The first step in his theory is that myocarditis can cause cardiomyopathy, but that in the vast majority of cases it does not. This general view was also expressed by Dr. O'Connell, and, while Astra argues against this proposition in its reply brief, it does not seem to be in serious dispute. To illustrate her point, plaintiff cites an authoritative text which states that myocarditis, while generally benign, can lead to congestive cardiomyopathy. II *The Heart* 1183 (J. Willis Hurst ed., 6th ed. 1986). Other articles, which plaintiff cites to show that Dr. Waller was not merely expressing an opinion but stating a recognized theory, state that there is "documented evidence of myocarditis as the condition responsible for the cardiomyopathy associated with

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[5] Astra did not challenge the admissibility of Dr. Waller's testimony on the grounds that it was not in conformity with a generally accepted explanatory theory, but Astra does challenge the propriety of the jury basing its verdict on Dr. Waller's testimony because of a defect in this regard.

pregnancy." K.R. Melvin et al., Peripartum Cardiomyopathy Due to Myocarditis, 307 *Medical Intelligence* 731, 733 (1982).[6]

The second step in Dr. Waller's theory is that ritodrine can unmask or aggravate myocarditis and thus, in combination, can cause cardiomyopathy. To support the second step, Dr. Waller relies primarily on the 1987 package insert accompanying ritodrine. The insert reads: "*Occult cardiac disease may be unmasked with the use of [ritodrine].*" Dr. Waller includes myocarditis in the definition of "cardiac disease." Astra maintains that myocarditis is not encompassed, yet, while questioning Dr. Waller, indicated that the risk of unmasking occult heart disease included the possibility of unmasking myocarditis.[7]

Dr. Waller was also of the opinion that ritodrine had a direct effect on plaintiff's heart. *See infra* section IV. The effect that ritodrine has on a patient's heart is acknowledged by Astra:

There have been serious cardiopulmonary complications including rarely maternal death associated with the use of betasympathomimetics in preterm labor.... The first observations

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[6] While Astra maintains that plaintiff's citations to authorities not in the record should be stricken, we find that unnecessary. Astra's claim is that Dr. Waller's testimony was opinion testimony not supported in science. Plaintiff's citations to these sources merely show that Dr. Waller's testimony was scientifically grounded.

[7] The colloquy between Astra's counsel and Dr. Waller, reads in pertinent part:

Q. [D]oesn't Astra Pharmaceutical say in the package insert that this drug can unmask occult heart disease right in the insert?

A. It certainly does.

Q. And ...

A. It emphasizes the danger of that drug.

Q. Yes, it does. And the physician is aware of those dangers when a physician prescribes such a drug, are they not?

A. Well, they're — as we talk about mitral valve prolapse, this is a very common entity....

Q. Doctor, *the occult heart disease I was referring to was myocarditis*.

A. That's all right. I would agree with the same statement with myocarditis.

(Emphasis added).

of serious complications were reported in 1976, and a number of reports have slowly increased since then. The most frequent observation is that of pulmonary edema with or without congestive heart failure.

(Trial testimony of Bruce Manning, Vice President of Astra, quoting Astra's Clinical Investigation Brochure.)

Beta-adrenergic drugs increase cardiac output; and even in a normal, healthy heart, this added myocardial oxygen demand can sometimes lead to myocardial ischemia. Complications may include: myocardial necrosis, which may result in death, arrhythmias, including premature atrial and ventricular contractions, ventricular tachycardia, and bundle branch block; anginal pain with or without ECG changes.

(Trial testimony of Dr. Peeno, quoting Astra's 1988 package insert.)

After a review of the record and the authorities cited by the parties, we find that Dr. Waller's testimony was within his area of expertise and was "sufficiently plausible to allow a jury to ground a verdict on it." *Turpin*, 959 F.2d at 1352. The evidence presented by Astra to support the theory that Tobin's peripartum cardiomyopathy was idiopathic or was caused solely by her myocarditis and twin pregnancy was an alternative theory of causation which was presented to the jury. The jury, in finding for the plaintiff, rejected defendant's proposed theory of causation and accepted Dr. Waller's theory.

III.

Having concluded that plaintiff's evidence of causation was appropriate expert testimony from which the jury could find causation, we turn to the two theories of liability offered by the plaintiff. The jury was instructed that it should find for the plaintiff if:

(a) ritodrine, as manufactured and marketed by Astra and as used by the plaintiff, was in a defective condition unreasonably dangerous to the user, and

(b) the defective and unreasonably dangerous condition of the ritodrine was a substantial factor in causing the plaintiff[']s[ ] injuries.

Or, if Astra failed to comply with the duty to exercise ordinary care to provide such warnings and instructions as would afford reasonable notice of the proper use and consequences of use of ritodrine.

> ...[A]nd that such failure was a substantial factor in causing the injuries sustained by the plaintiff....

Separate verdict forms were used for each theory of liability, and the jury found Astra liable under both theories.

A.Failure to Warn

Astra argues that under Kentucky law it was error to submit a separate instruction on failure to warn, because the nature of the warning is one of several factors to be considered on the issue of product defect. *Montgomery Elevator Co.* v. *McCullough*, 676 S.W.2d 776, 780-781 (Ky. 1984). Indeed, the design defect instruction given to the jury included the statement:

> In determining whether the ritodrine was in a defective condition unreasonably dangerous to the user, you may consider the adequacy of the warnings and instructions for use set forth in the package insert and in the *Physician's Desk Reference*. A warning is adequate if it affords fair and adequate notice of the possible consequences of use of the product.

However, under Kentucky law, when a plaintiff has made a claim of negligence in addition to a product defect claim, a separate "negligence instruction is warranted." *Ingersoll-Rand Co.* v. *Rice*, 775 S.W.2d 924, 932 (Ky. Ct. App. 1989). The instruction on Astra's duty to warn was a negligence instruction, using the standard of "ordinary care," and expressly explained that phrase to the jury. Therefore, Astra's challenge to the separate instruction is rejected.

Astra next argues that plaintiff's failure to warn theory was legally insufficient, in that the only duty a manufacturer has is to

warn of known risks. *Watters* v. *TSR, Inc.*, 904 F.2d 378, 381 (6th Cir. 1990). Astra argues that the risk of developing cardiomyopathy was unknown and therefore it was not required to warn of the possibility. Astra's arguments on this point miss the mark. Plaintiff's failure to warn theory was not based on a failure to warn that ritodrine may cause cardiomyopathy, but that Astra breached its duty to warn by not explicitly listing mitral valve prolapse as a contraindication for use, and by not giving adequate instructions for use.

Mitral Valve Prolapse

Astra considers mitral valve prolapse to be a contraindication, and believes it is encompassed by the warning in the package insert listing "maternal cardiac disease" as a contraindication. Dr. Waller testified that obstetricians do not understand "cardiac disease" to include mitral valve prolapse.

"[Mitral valve prolapse] is a very common entity; and obstetricians/gynecologists, their focus in medicine is taking care of pregnant ladies; and they're experts in that area.... They consider, as I mentioned before, the mitral valve prolapse, a benign problem. It's not. So simply indicating a caution for heart disease, that's really inadequate. It doesn't provide the patient maximum care. It doesn't give the doctor the best information available."

Given the fairly common occurrence of mitral valve prolapse in women of child bearing age, it was within the jury's province to conclude that failure to separately list mitral valve prolapse as a contraindication was a breach of Astra's duty to warn.

Astra argues that, even if the failure to specifically list mitral valve prolapse as a contraindication was a failure to warn, it does not trigger liability in this case because that failure did not cause Tobin's injury. On this point we agree with the defendant. Plaintiff's own expert, Dr. Waller, testified that plaintiff's mitral valve prolapse was not a substantial factor in causing her cardiomyopathy:

Q. Do you have an opinion that the mitral valve prolapse aggravated her myocarditis?

A. I would say it did not in a primary sense. In an indirect sense, it causes premature ventricular contractions, which are ineffectual heart beats which diminish the blood supply to the heart. So in a minor way, it's contributing to the cardiomyopathy.

. . . .

Physiologically it has an adverse effect in terms of—in the presence of Ritodrine, we're not asking the heart to move more forcefully, contract strongly—more stronger and the heart beat go faster. This will make the prolapse worse and make extra heart beats more common.

Adequate Instructions for Safe Use

Plaintiff's other argument regarding failure to warn relates to the studies on efficacy of ritodrine. Plaintiff argues that, because the duty to warn includes the duty to provide adequate instructions for safe use, *Post* v. *American Cleaning Equip. Corp.*, 437 S.W.2d 516, 521 (Ky. Ct. App. 1968), the warnings Astra provided were deficient because they "failed to inform physicians that ritodrine has not been proven effective in extending pregnancy beyond 24 to 48 hours, nor in improving neonatal outcome." Plaintiffs are essentially arguing that the package insert should have included a warning that ritodrine is not effective. We prefer to analyze the evidence regarding efficacy under the second theory of liability presented to the jury—defective product design, unreasonably dangerous to the user.

B. Strict Liability — Defective Design

Under Kentucky law, the test for whether a product is in a defective condition and unreasonably dangerous to the user is whether an ordinarily prudent manufacturer, being fully aware of the risks, would have placed the product on the market. *Nichols* v. *Union Underwear Co.*, 602 S.W.2d at 429, 433 (Ky. 1980). Plaintiff argues that the only way to decide whether an ordinarily prudent manufacturer would place a product on the market is to balance the product's risks, its harmful side effects, against its benefits. Defendant argues that Kentucky has never adopted the risk/benefit analysis proffered by plaintiff. To support its position, defendant cites *Ingersoll-Rand*, 775 S.W.2d at 932, where the

Kentucky Court of Appeals stated it was "disturbed by the risk/benefit analysis provided in" a jury instruction. Defendant fails to note two critical points.

First, the *Ingersoll-Rand* court specifically stated that it was not expressing an opinion on the appropriateness of the "risk/benefit analysis" instruction in future cases, but that in the case before it such an instruction was not appropriate, because "[t]here was simply no evidence before the jury in this case which would allow the jury to evaluate the risks and benefits associated with the design and manufacture of [the product] in order for them to use this instruction in any meaningful way." *Id.* at 933. In the case at bar, evidence of the risks and benefits associated with ritodrine were a main focus of the case. Second, the jury in this case was not given a "risk/benefit analysis" instruction; it was given the standard strict liability instruction, approved in Kentucky. Thus, *Ingersoll-Rand* is inapplicable.

As summarized by the Kentucky Supreme Court, the standard for strict liability is formulated:

The manufacturer is *presumed to know* the qualities and characteristics, and the actual condition, of his product at the time he sells it, and the question is whether the product creates "such a risk" of an accident of the general nature of the one in question "that an ordinarily prudent company engaged in the manufacture" of such a product "would not have put it on the market."

Montgomery Elevator, 676 S.W.2d at 780 (quoting *Nichols*, 602 S.W.2d at 433). In the context of her defective design claim, plaintiff's arguments regarding the weighing of the risks against the benefits of ritodrine were not improper, given the evidence presented in this case. The district judge did not instruct the jury to weigh the risks against the benefits, but only instructed them that "ritodrine was in a defective condition unreasonably dangerous to the user if an ordinarily prudent manufacturer of such a drug, being fully aware of the risks associated with the use of ritodrine, would not have put the drug on the market." The instruction that was given is consistent with Kentucky law.

In a nutshell, Plaintiff claims that oral ritodrine is bereft of benefits as far as improving neonatal outcome.[8] Weighing no benefits against the serious risks posed by the drug and suffered by the plaintiff, it is clear, plaintiff asserts, that the risks outweigh the benefits and thus no "ordinarily prudent manufacturer" would put the drug on the market. Astra maintains that oral ritodrine is effective in prolonging pregnancy, and therefore in improving neonatal outcome, and that the risks to maternal and fetal health associated with oral ritodrine are outweighed by the benefits of reducing neonatal morbidity and mortality. Astra also maintains that, because of FDA approval, ritodrine's effectiveness is not open to question.

Plaintiff's expert in this area was Dr. Mortensen. Dr. Mortensen, a pediatrician with a master's degree in pharmacology and trained in toxicology, reviewed the test results that were submitted to the FDA with the New Drug Application in 1974. Dr. Mortensen also reviewed several articles discussing betamimetic drugs in general and ritodrine in specific. Defendant objected to Dr. Mortensen being allowed to testify as an expert on these issues, but that objection was overruled. Defendant argues that Dr. Mortensen did not possess sufficient qualifications to testify regarding the efficacy of ritodrine. However, the two cases defendant cites in this regard are not helpful. *Sterling* v. *Velsicol Chemical Corp.*, 855 F.2d at 1208, concerns the criterion for admission of expert testimony that it be in conformity to a generally accepted explanatory theory, not the required qualifications of an expert. *Rohrbough* v. *Wyeth Laboratories, Inc.*, 916 F.2d 970, 975 (4th Cir. 1990), also does not address the qualifications a person should possess to qualify as an expert. Dr. Mortensen has experience in clinical studies on the efficacy of drugs. Her testimony centered on the testing procedures used in various studies of the efficacy of ritodrine and the interpretation of the test results. Her testimony on the clinical studies investigating ritodrine was properly allowed.

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[8] Plaintiff does acknowledge that there may be some benefit in improving the overall quality of life for the mother during the remainder of the pregnancy by avoiding repetitive hospitalization.

Before addressing the arguments concerning efficacy, we must first address whether plaintiff should have been allowed to litigate the efficacy issue at all. Defendant argues that "[p]laintiff should not have been permitted to litigate this issue, because it is a mockery of the scientific analysis employed by the FDA and the Advisory Committee which conclusively found that ritodrine was efficacious." We reject the argument that FDA approval preempts state product liability claims based on design defect. While this circuit has not directly ruled on whether a plaintiff in a product liability action may litigate an FDA finding that a drug is efficacious, the Fifth Circuit has ruled that the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, does not preempt state law claims based on defective design. *Hurley* v. *Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1989). In so holding, the Fifth Circuit reversed the district court's finding of preemption, noting that "the great majority of United States district courts which have addressed this issue have ruled against preemption." *Id.* at 1176 (footnote omitted).

FDA approval is evidence which the jury may consider in reaching its verdict. The jury may weigh FDA approval as it sees fit, especially in a case where the plaintiff has presented evidence to support an articulable basis for disregarding an FDA finding—in this case the finding that ritodrine was effective. *Tobin* presented an articulable basis for disregarding the FDA's finding that ritodrine was effective in improving neonatal outcome: the individual studies relied on by the FDA were insufficient to support a finding of efficacy as found by the FDA Advisory Committee, and the pooled data requested by the Advisory Committee was statistically invalid.

To understand the arguments of the parties concerning ritodrine's effectiveness, it is necessary to review the New Drug Application that was submitted to the FDA and the results of the required clinical trials, along with subsequent articles that have been published discussing ritodrine. Approval of a new drug by the FDA requires a showing of substantial evidence of efficacy based upon adequate and well-controlled studies. The required clinical studies on ritodrine consisted of Phase I (16 studies in healthy patients to determine safety), Phase II (5 studies in preterm labor

patients to determine efficacy), and Phase III (11 studies in preterm labor patients comparing ritodrine patients to non-ritodrine controls to determine safety and efficacy).

The clinical trials were designed to measure a gain in days in the length of pregnancy as a measure of efficacy under the assumption that any increase in the gestational period would reduce neonatal morbidity and mortality. The Phase III studies consisted of tests of oral ritodrine's effectiveness based on three separate testing procedures: a placebo series, in which oral ritodrine was compared to the use of a placebo; an ethanol series comparing ritodrine to the use of ethanol; and a series referred to as the "Creasy studies," in which all patients were treated with injections of intramuscular ritodrine and then half received oral maintenance doses of ritodrine while the other half received placebos. In the Creasy studies, any recurrences of premature labor were treated with injections of intramuscular ritodrine.

After the data from these studies was submitted to the FDA, the FDA Advisory Committee on Fertility and Maternal Health Drugs found that the required clinical trials failed to demonstrate efficacy. Specifically, "the tenor of the committee was that there was not substantial data to support the efficacy of ritodrine for the treatment of premature labor." The Advisory Committee found that three of the Phase III placebo-controlled studies were flawed because they included women who were not actually in preterm labor. Because the remaining individual studies did not have a sufficient number of patients to establish statistical significance regarding improvement in neonatal outcome, the Advisory Committee requested the data be pooled and resubmitted. The initial data was presented in terms of gain in days; it did not include statistics on neonatal outcome or mortality. The Advisory Committee requested that, when the data was resubmitted, it should include such information. The manufacturer was asked to pool the data from all the studies for an all-patient analysis; stratify all of the patients by gestational age; and analyze neonatal mortality, birth weight, and the incidence of respiratory distress syndrome.

Dr. Peter, who participated in the proceedings before the FDA, testified at trial that this pooled data does not represent

statistically valid results. Dr. Barden, one of Astra's experts, said he was not surprised that one of the members of the advisory committee stated the pooled studies were not statistically valid,

[b]ecause the problem with pooled studies, as you well know, were that some of the patients had rather than placebo, the treatment with ethanol or alcohol, which is another treatment of premature labor. So that tends to mean that by pooling the data, they were mixing apples and oranges in a sense.

Comments made by various members of the Advisory Committee recognized the inappropriateness of pooling data: "So, strictly speaking, the statistical tests are not valid for the pooled studies. The statistical tests would presume that the groups randomized were similar in every respect but for the treatments received, and here we have a combination of different controls and different treatment regimes for ritodrine patients." Dr. Little of the committee commented that "obviously, it is not reasonable to pool data." Yet, on the basis of the originally submitted data, which the Advisory Committee had found did not contain substantial evidence to support a finding of efficacy, and the newly reworked data, the committee recommended approval.

The FDA made its own determination regarding efficacy. FDA regulations require that efficacy be established by "at least two 'adequate and well controlled' studies." *Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147, 151 (3d Cir. 1986). The FDA determined that four studies of the Phase III studies met this test, and approved ritodrine in 1980. The four studies referred to by the names of the project leaders: Fuchs, Barden, Creasy and Sivasambo. Plaintiff introduced evidence regarding the methodology and conclusions of each study.

In the Fuchs study, the control group of mothers were treated with intravenous ethanol and no follow-up, while ritodrine patients were given initial intravenous doses of ritodrine and follow-up oral doses. The control group was further along in gestation based on each mother's last menstrual period, and the group was found to be in more advanced labor, in that they were more dilated, than the ritodrine group. The Savasambo study compared ritodrine to librium, which according to recent studies actually increases uterine

activity. The Creasy study, described above, did not have an adequate control group, in that all patients were given intramuscular injections of ritodrine at the onset of premature labor and again if the contractions returned. In a later publication, Dr. Creasy stated that "further studies have not proved that oral maintenance will decrease the incidence of preterm birth.... [T]hey do show that such an approach will decrease the need for repetitive hospitalization, thus improving the overall quality of life for the remainder of the pregnancy." The final study relied on by the FDA, the Barden study, involved a total of only 25 patients—some given oral ritodrine and others given a placebo.

Astra's evidence focused on the effect of oral ritodrine in prolonging the term of pregnancy, and then separately showed that extending the term of pregnancy improves neonatal outcome. Plaintiff refuted this claim with evidence that, while ritodrine may produce a short-term gain in prolonging pregnancy, there is no evidence of improved neonatal outcome. Plaintiff introduced articles written after the FDA approval. One of those articles concluded that "the lack of any suggestion of an effect on [neonatal] mortality and respiratory morbidity remains noteworthy, particularly given the clear short-term effect of tocolytic treatment on duration of gestation." James F. King *et al.*, *Beta-mimetics in preterm labour — an overview of the randomized controlled trials*, 95 British Journal of Obstetrics and Gynecology 211, 220 (1988). Other articles have come to similar conclusions:

> Although ritodrine treatment delayed delivery for 24 hours, it did not significantly modify the ultimate perinatal outcomes after preterm labor. These observations may be explained by the recent reports that describe ... [beta]-agonist uterine-relaxant effects are too transient to impede preterm labor significantly; the national data on the incidence of LBW [low birth weight] infants provide further support for this observation.

Kenneth J. Leveno *et al.*, *The National Impact of Ritodrine Hydrochloride for Inhibition of Preterm Labor*, 76 Obstetrics and Gynecology 12, 14 (1990).

> The results with ritodrine are imprecise and uncertain and not worth the risk of a major reaction.

....

> Despite the use of betamimetics in Europe for about 20 years, there is no objective evidence that the incidence of prematurity has been reduced. The same statement holds in the United States after 8 years of use.
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> ....
>
> Ritodrine is a very potent drug that has side effects that are extremely disturbing and may be lethal.

Edward A. Garber *et al.*, *Dilemmas in the Pharmacological Management of Preterm Labor*, 44 Obstetrical and Gynecological Survey 512, 514-16 (1989).

In diversity actions, state law governs the grants and denials of motions for judgment n.o.v. *Bank of Cumberland* v. *Aetna Casualty & Surety Co.*, 956 F.2d 595, 597 (6th Cir.), *cert. denied*, 113 S. Ct. 204 (1992). "In evaluating a JNOV under Kentucky law a trial court is required to consider the evidence in the strongest possible light in favor of the party opposing the motion and must give the opposing party the advantage of every fair and reasonable inference that can be drawn from the evidence." *Id.* As a question of law, we review *de novo* the grant or denial of a motion for judgment n.o.v. *See Toth* v. *Yoder Co.*, 749 F.2d 1190, 1194 (6th Cir. 1984).

We do not sit to review the findings of the FDA; our only role in this appeal is to decide if there was sufficient evidence on which the jury could base its verdict. Plaintiff introduced evidence, through the cross-examination of Astra officials, that a reasonably prudent manufacturer would not market ritodrine if the evidence of its efficacy was inconclusive. Plaintiff also introduced sufficient evidence regarding the various clinical studies concerning the efficacy of ritodrine. The jury found that ritodrine, as manufactured and marketed by Astra, was in a defective condition and unreasonably dangerous to plaintiff. We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market ritodrine.

Defendant argues that if the warning accompanying ritodrine was adequate then it cannot be held strictly liable. The cases cited

by defendant to support its position, that a drug manufacturer should be shielded from liability, so hold based on comment k of the Restatement (Second) of Torts § 402A. Comment k provides that the seller of "unavoidably unsafe products" "is not to be held to strict liability for unfortunate consequences attending their use...." For comment k to apply, however, the product must be "an apparently useful and desirable product." It is the useful or effective nature of ritodrine which plaintiff has called into question. Kentucky has ruled that comment k shields manufacturers from liability for "highly useful and desirable product[s] attended with a known but reasonable risk." *McMichael* v. *American Red Cross*, 532 S.W.2d 7, 9 (Ky. 1975) (citing comment k). A drug that prolongs pregnancy in order to reduce infant morbidity and mortality, if effective, is a highly useful and desirable product.[9] Plaintiff, however, has attacked the linchpin of this theory — effectiveness — with various evidence. The jury was instructed:

A product such as ritodrine is not in a defective condition unreasonably dangerous if it cannot be made completely safe for all users, but is nevertheless a useful and desirable product which is accompanied by proper directions and warnings.

The jury verdict rejecting this argument is supported by the evidence that was presented.

IV.

Astra argues that it is entitled to a new trial based on what Astra terms an undisclosed change in expert testimony. Dr. Waller was deposed approximately one year prior to trial. In his letter report to plaintiff's counsel, he stated that "cardiomyopathy resulting directly from the use of Ritodrine is an extremely remote etiology" and was the "least likely and least provable from a scientific standpoint." The night before he was to testify Dr.

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[9] Premature labor contractions occur in approximately 10 percent of pregnant women. The problems associated with preterm delivery are numerous: low birth weight, birth defects, respiratory distress syndrome, high infant morbidity and mortality, etc. The parties agree that bed rest is effective in 50 percent of patients showing signs of premature labor.

Waller informed plaintiff's counsel that he had "moved up" this hypothesis to a more likely explanation, based on subsequently discovered literature he claimed evidenced a direct toxic effect on the heart and examinations of slides of Tobin's explanted heart. Plaintiff's counsel did not examine Dr. Waller on this theory. Other than a brief reference in Dr. Waller's opening comments,[10] this theory was not discussed until Astra raised the issue on cross-examination. Having raised the issue, Astra was then able to impeach Dr. Waller's new "ranking" of probable causation with his prior statements in his deposition and letter.

Defendant moved to strike Dr. Waller's testimony. The district court found that, while not disclosing this change in testimony sooner was a clear violation of the rules, it was of short duration (the change in opinion was withheld during the morning prior to defense counsel engaging in cross-examination), and there was no proof of knowing concealment. "The burden of showing harmful prejudice rests on the party seeking the new trial." *Clarksville-Montgomery County School Sys.* v. *United States Gypsum Co.*, 925 F.2d 993, 1002 (6th Cir. 1991). The only prejudice offered to the district court was that Astra had no opportunity to employ a cardiologist to refute the new opinions articulated by Dr. Waller. The district court recognized that there were other more appropriate remedies, short of striking Dr. Waller's testimony, to correct any prejudice that might have occurred. Specifically, the court noted that Astra had not made a motion seeking a continuance or additional time to employ a cardiologist, or to take further depositions of Dr. Waller and then present more cross-examination. Indeed, the court even stated on the record that it would "certainly entertain a request from Astra to have additional time to probe this matter with its own experts if Astra so desires.... Astra never availed itself of this option. See *K.M.C. Co.* v. *Irving Trust Co.*, 757 F.2d 752, 765-66 (6th Cir. 1985) (rejecting complaint of surprise and prejudice when no attempt to cure by seeking continuance was made).

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[10] At the beginning of direct examination, Dr. Waller stated that "Ritodrine administered to Kathy Tobin will have a direct effect on the production of cardiomyopathy, which led to her cardiac transplantation."

Astra admitted at oral argument that it made a strategic decision to not seek a continuance. It cannot now argue that it is entitled to a new trial because of any prejudicial effect of Dr. Waller's change in testimony, testimony on which plaintiff did not rely but was only thoroughly brought out in cross-examination.

V.

Defendant next argues that it is entitled to a new trial because Dr. Mortensen relied on articles and clinical results not directly listed as ones on which she would rely. At the time of Dr. Mortensen's deposition, she had reviewed portions of the individual Phase III studies and selected two articles which she relied upon to support her opinions. By the time of trial, she had reviewed all of the individual Phase III studies, as well as the pooled data and the Advisory Committee transcript. Additionally, she had reviewed a number of articles not mentioned in her deposition. All of these items were listed in plaintiff's exhibit list. Again, Astra did not seek a continuance or even, in the case of Dr. Mortensen, move to strike.[11] Defendant has failed to show such prejudice as would warrant the grant of a new trial.

VI.

Finally, Astra argues the verdict was against the great weight of the evidence and therefore its motion for a new trial should have been granted. In a diversity action, the question of whether a new trial should be ordered is determined with reference to federal procedural law. *Toth*, 749 F.2d at 1197. In ruling upon a motion for a new trial challenging the weight of the evidence, the trial court's obligation is to compare the opposing proofs, weigh the evidence, and set aside the verdict if it is of the opinion that the verdict is against the clear weight of the evidence. It should deny the motion if the verdict is one which could reasonably have been

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[11] Astra did object to Dr. Mortensen testifying on the grounds that by the time of trial she had reviewed more material than she had reviewed at the time of her deposition.

reached, and the verdict should not be considered unreasonable simply because different inferences and conclusions could have been drawn or because other results are more reasonable.

J.C. Wyckoff & Assocs. Inc. v. *Standard Fire Ins. Co.*, 936 F.2d 1474, 1487 (6th Cir. 1991) (citations omitted). We review grants and denials of motions for new trials under an abuse of discretion standard. *Toth*, 749 F.2d at 1197. "Abuse of discretion is defined as a definite and firm conviction that the trial court committed a clear error of judgment." *Logan* v. *Dayton Hudson Corp.*, 865 F.2d 789, 790 (6th Cir. 1989). We already have concluded that there was sufficient evidence to support the jury's verdict finding defendant liable for plaintiff's injury. The district court's denial of defendant's motion for a new trial was not an abuse of discretion. We affirm.

VII.

Plaintiff appeals the dismissal of Duphar B.V., the manufacturer of ritodrine based in the Netherlands, for lack of personal jurisdiction. The district court found that Duphar had not purposely availed itself of the privilege of conducting activities in the forum state of Kentucky. The district court relied extensively on the plurality opinion in *Asahi Metal Industries Co.* v. *Superior Court*, 480 U.S. 102 (1987). The *Asahi* plurality stated that merely placing a product into the stream of commerce, even with awareness that it may reach the forum state, does not establish sufficient minimum contacts for personal jurisdiction. *Id.* at 112. Rather, according to the plurality, the manufacturer must engage in some "[a]dditional conduct." *Id.* The district court found that defendant Duphar had not engaged in any such additional conduct and thus was not subject to the personal jurisdiction of the court.

VIII.

The decision to exercise personal jurisdiction is a question of law based on the Due Process Clause of the Constitution. *Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462, 471-72 (1985). As a question of law, we review *de novo* challenges to a court's decision

to exercise personal jurisdiction. *See Dakota Indus.* v. *Dakota Sportswear*, 946 F.2d 1384, 1387 (8th Cir. 1991); *Madara* v. *Hall*, 916 F.2d 1510, 1514 (11th Cir. 1990). In a diversity action, a federal court examining whether jurisdiction exists "must look to the forum state's long-arm statute and must construe that statute within the bounds of the due process clause." *R.L. Lipton Distrib.* v. *Dribeck Importers, Inc.*, 811 F.2d 967, 969 (6th Cir. 1987). In this case, the Kentucky long-arm statute provides:

> (2) (a) A court may exercise personal jurisdiction over a person who acts directly or by an agent, as to a claim arising from the person's:
>
> ....
>
> 4. Causing tortious injury in this Commonwealth by an act or omission outside this Commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth ... ;
>
> 5. Causing injury in this Commonwealth to any person by breach of warranty expressly or impliedly made in the sale of goods outside this Commonwealth when the seller knew such person would use, consume, or be affected by, the goods in this Commonwealth, if he also regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth[.]

Ky. Rev. Stat. Ann. § 454.210(2)(a). The Court of Appeals of Kentucky, then the highest court of the commonwealth, recognized that this long-arm statute "was designed to extend the permissible scope of jurisdiction over foreign corporations with minimal contact in Kentucky." *Ford Motor Credit Co.* v. *Nantz*, 516 S.W.2d 840, 842 (Ky. 1974). The Kentucky long-arm statute has been understood to reach the limit permitted by the Constitution. *Handley* v. *Indiana & Michigan Elec. Co.*, 732 F.2d 1265, 1271 (6th Cir. 1984) (citing *Poyner* v. *Erma Werke GMBH*, 618 F.2d 1186, 1192 (6th Cir.), *cert. denied*, 449 U.S. 841

(1980)). Thus, the single issue is whether the jurisdiction sought is within the requirements of due process.

We have historically employed the following criteria to determine if personal jurisdiction is appropriate:

First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Theunissen v. *Matthews*, 935 F.2d 1454, 1460 (6th Cir. 1991) (citing *Southern Machine Co.* v. *Mohasco Indus.*, 401 F.2d 374, 381 (6th Cir. 1968)). If these criteria are satisfied, jurisdiction is appropriate if "maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *International Shoe Co.* v. *Washington*, 326 U.S. 310, 316 (1945) (citation omitted).

The burden of establishing jurisdiction is on the plaintiff. *Theunissen*, 935 F.2d at 1458. Here, it is not disputed that Duphar manufactures the drug that plaintiff alleges caused her injury. It also is not disputed that in 1974 Duphar submitted to the FDA a New Drug Application to obtain approval of the drug for sale in the United States. Duphar came to the United States and conducted clinical studies to further the FDA's approval of the drug. The *Asahi* plurality recognized that "designing the product for the market in the forum State" can indicate an intent or purpose to serve the forum state. *Asahi*, 480 U.S. at 112. Duphar maintains that FDA approval was merely a prerequisite for placing the product into the stream of commerce. Duphar confuses the stream of commerce concept. Duphar's direct efforts in obtaining FDA approval allowed Duphar to avail itself of the vast, lucrative markets of each state in the United States.

During the same time as the FDA approval process, Duphar sought out and negotiated a licensing agreement with defendant Astra Pharmaceuticals. Under that agreement, Astra was to distribute the drug throughout its "territory," defined in the agreement as "the United States of America, its territories and

possessions, and Puerto Rico." Article III, paragraph (2)(c) of the "Continuing Technical Information Exchange Agreement" provides:

> Astra will be solely responsible for compliance with all applicable FDA requirements concerning the processing and marketing approval with respect to the therapeutic use of the Product in human beings for the treatment of premature labor or decrease of uterine activity. Astra will regularly consult with DUPHAR as to its dealings with the FDA and obtain DUPHAR's advice and agreement (such agreement not to be unreasonably delayed or withheld by DUPHAR) prior to submitting to the FDA any information on the Product, its labeling, package inserts or otherwise.

Duphar claims, because Astra was "solely responsible," that "control" of the package insert resided with Astra, while plaintiff maintains that requiring Duphar's agreement before submitting information to the FDA placed ongoing control over the package insert in Duphar's hands. Following the clear language of the quoted clause, we find plaintiff's argument correct. Duphar intended to keep tight control over the information given to the FDA and over any changes in the wording of the package insert. In its brief, Duphar notes it must consider the impact any such activity in the United States might have on the marketing of ritodrine in more than 40 other countries. The widespread impact such activity could have is strong motivation for Duphar to keep a firm guiding hand on Astra's activities.

Even under the test set forth in the plurality opinion of *Asahi*, relied on by both Duphar and the district court, Duphar has contact that is "something more" than mere awareness that the stream of commerce will sweep the product into the forum state. *Asahi*, 480 U.S. at 111-12. Duphar made a *deliberate decision* to market ritodrine in all 50 states, including Kentucky, the forum state. See *id.* at 112 (citing *Max Daetwyler Corp.* v. *R. Meyer*, 762 F.2d 290, 299 (3d Cir. 1985)). Duphar did not, for example, seek a "New England regional distributor" or a distributor for specific states. It sought and obtained a distributor to market its product in each and every state. Even the *Asahi* plurality recognized that

"marketing the product through a distributor who has agreed to serve as the sales agent in the forum State" can "indicate an intent or purpose to serve the market in the forum State." 480 U.S. at 112. Duphar arguably also kept control over an essential element of the product — the package insert.

We find helpful the reasoning of *Mott* v. *Schelling & Company*, No. 91-1540, 1992 U.S. App. LEXIS 13273 (6th Cir. May 29, 1992). In *Mott*, we affirmed the exercise of personal jurisdiction over the defendant, Schelling, the Austrian designer and manufacturer of an industrial saw that injured the plaintiff. Noting that Schelling sold saws all over the world and maintained an exclusive American sales agent, we found significant the fact that United States standards were taken into account in the design and manufacture of the saw at issue. Additionally, we recognized that the product was available only through the United States distributor.

Schelling knew its saws were being sold in the United States. The company actively cultivated its market here, and benefited from numerous U.S. sales, including the one in this case, over many years. Clearly Schelling cannot reasonably expect to sell a potentially dangerous product into the United States, exact its price, and then shirk any obligations that arise when its machine goes awry. Due process does not require us to allow Schelling to exploit this country's vast, rich markets and at the same time avoid the jurisdiction of our courts. Under any formulation of the test, the district court properly exercised personal jurisdiction over Schelling.

Id. at 17-18. As in *Mott*, defendant Duphar cannot expect to rely solely on the use of an independent distributor to insulate it from suit. *Poyner*, 618 F.2d at 1190. Duphar did not merely sell its product on the market with no direction in mind. Duphar directly submitted a New Drug Application to the FDA for approval, conducted clinical studies in the United States, and sought out a United States distributor to exploit the United States market. In this context, Duphar was not simply placing its product into the stream of commerce. Duphar purposefully availed itself of the privilege of conducting business in all states, including the State

of Kentucky. As we have stated many times before, "[p]urposeful availment by the defendant of the privilege of acting in, or causing consequences in, the forum state 'is the *sine qua non* of *in personam* jurisdiction.'" *Theunissen*, 935 F.2d at 1460 (citation omitted).

Duphar argues that it has done nothing in particular to purposefully avail itself of the Kentucky market as distinguished from any other state in the union. If we were to accept defendant's argument on this point, a foreign manufacturer could insulate itself from liability in each of the fifty states simply by using an independent national distributor to market its products, a result we specifically rejected in *Poyner*. Duphar cannot deny that by licensing Astra to distribute ritodrine in all fifty states it employed the distribution system that brought ritodrine to Kentucky. See *Asahi*, 480 U.S. at 112-13 (citing *Hicks* v. *Kawasaki Heavy Indus.*, 452 F. Supp. 130 (M.D. Pa. 1978)).

The second element in our three-part test for personal jurisdiction, articulated in *Southern Machine*, 401 F.2d at 381, is satisfied. Plaintiff's cause of action arose from defendant's activities in causing ritodrine to be sold in Kentucky.

Finally, we must inquire whether the exercise of jurisdiction over the defendant would "offend 'traditional notions of fair play and substantial justice.'" *International Shoe Co.* v. *Washington*, 326 U.S. 310, 316 (1945) (citation omitted). We have noted that once the first two criteria of the *Southern Machine* test are satisfied an inference arises that the third — fairness — is also present; only the unusual case will not meet this third criterion. *Theunissen*, 935 F.2d at 1461. The determination of reasonableness depends on an evaluation of several factors: the burden on the defendant of litigating in the forum, the interest of the forum state, the plaintiff's interest in obtaining convenient and effective relief, and the shared interest of the several states in furthering fundamental substantive social policies. *World Wide Volkswagen Corp.* v. *Woodson*, 444 U.S. 286, 292 (1980). When the case involves a non-resident alien defendant, significant weight must be given to the unique burdens placed upon one who must defend oneself in a foreign legal system. *Asahi*, 480 U.S. at 114. Duphar has shown

its familiarity with the United States administrative and legal process by undergoing the formidable task of obtaining FDA approval for ritodrine. While this prior activity does not lessen the burden on Duphar to litigate in the United States, it does indicate that Duphar will not be lost in our complex legal system and shows a willingness by Duphar to expend substantial resources to exploit the United States market.

In the present case the exercise of jurisdiction is reasonable. The interests of the forum state and the plaintiff are quite high. A Kentucky resident has been injured, allegedly by a product manufactured by defendant. In this respect, the present case is not similar to *Asahi*. The claim presented in *Asahi* was a third-party action for indemnification by a Taiwanese manufacturer of a defective motorcycle tire against a Japanese manufacturer of a tire valve stem. In *Asahi*, California's interest in the case was minor, because the underlying personal injury claim brought by the California resident had been settled. *Id.* In the present action, Kentucky's interest remains significant.

In *Asahi*, the Supreme Court recognized that, "[w]hen minimum contacts have been established, often the interests of the plaintiff and the forum in the exercise of jurisdiction will justify even the serious burdens placed on the alien defendant." *Id.* This is such a case.

IX.

We AFFIRM the district court's denial of defendant Astra's motion for judgment notwithstanding the verdict or in the alternative for a new trial.

We REVERSE the grant of defendant Duphar's motion to dismiss for lack of personal jurisdiction.

APPENDIX F

Judgment of the Court of Appeals
Entered April 16, 1993

Nos. 91-6413/6478

United States Court of Appeals

For the Sixth Circuit

KATHY D. TOBIN,
Plaintiff-Appellee (91-6413),
Plaintiff-Appellant (91-6478),

v.

ASTRA PHARMACEUTICAL PRODUCTS, INC.,
Defendants-Appellant (91-6413),

DUPHAR, B.V.,
Defendant-Appellee (91-6478).

JUDGMENT

ON APPEAL from the United States District Court for the Western District of Kentucky at Louisville.

THIS CAUSE was hear on the record from the district court and was argued by counsel.

ON CONSIDERATION WHEREOF, it is ordered that the district court's denial of defendant Astra's motion for judgment notwithstanding the verdict or in the alternative for a new trial is affirmed. IT IS FURTHER ORDERED that the district court's order granting defendant Duphar's motion to dismiss for lack of personal jurisdiction is reversed.

ENTERED BY ORDER OF THE COURT

/s/ LEONARD GREEN, JR.
CLERK

APPENDIX G

Order of the Court of Appeals denying Petition for Rehearing entered May 13, 1993

Nos. 91-6413/6478

United States Court of Appeals

For the Sixth Circuit

KATHY D. TOBIN,
Plaintiff-Appellee (91-6413),
Plaintiff-Appellant (91-6478),

v.

ASTRA PHARMACEUTICAL PRODUCTS, INC.,
Defendants-Appellant (91-6413),

DUPHAR, B.V.,
Defendant-Appellee (91-6478).

BEFORE: GUY and RYAN, Circuit Judges; CHURCHILL, District Judge.

Upon consideration of the petition for rehearing filed by the appellant,

It is ORDERED that the petition for rehearing be, and it hereby is, DENIED.

ENTERED BY ORDER OF THE COURT

/s/ LEONARD GREEN, JR.
CLERK

APPENDIX H

Constitutional and Statutory Provisions Involved

THE UNITED STATES CONSTITUTION

The Due Process Clause of the Fourteenth Amendment

No State shall . . . deprive any person of life, liberty or property, without due process of law . . . .

TITLE 28 OF THE UNITED STATES CODE

§ 1332. Diversity of citizenship; amount in controversy; costs

(a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $50,000, exclusive of interest and costs, and is between —

(1) citizens of different States;

(2) citizens of a State and citizens or subjects of a foreign state;

(3) citizens of different States and in which citizens or subjects of a foreign state are additional parties; and

(4) a foreign state, defined in section 1603(a) of this title, as plaintiff and citizens of a State or of different States.

For the purposes of this section, section 1335, and section 1441, an alien admitted to the United States for permanent residence shall be deemed a citizen of the State in which such alien is domiciled.

(b) Except when express provision therefor is otherwise made in a statute of the United States, where the plaintiff who files the case originally in the Federal courts is finally adjudged to be entitled to recover less than the sum or value of $50,000, computed without regard to any setoff or counterclaim to which the defendant may be adjudged to be entitled, and exclusive of interest and costs, the district court may deny costs to the plaintiff and, in addition, may impose costs on the plaintiff.

(c) For the purposes of this section and section 1441 of this title —

(1) a corporation shall be deemed to be a citizen of any State by which it has been incorporated and of the State where it has its principal place of business, except that in any direct action against the insurer of a policy or contract of liability insurance, whether incorporated or unincorporated, to which action the insured is not joined as a party-defendant, such insurer shall be deemed a citizen of the State of which the insured is a citizen, as well as of any State by which the insurer has been incorporated and of the State where it has its principal place of business; and

(2) the legal representative of the estate of a decedent shall be deemed to be a citizen only of the same State as the decedent, and the legal representative of an infant or incompetent shall be deemed to be a citizen only of the same State as the infant or incompetent.

(d) the word "States", as used in this section, includes the Territories, the District of Columbia, and the Commonwealth of Puerto Rico.

(As amended July 26, 1956, c. 740, 70 Stat. 658; July 25, 1958, Pub. L. 85-554, § 2, 72 Stat. 415; Aug. 14, 1964, Pub. L. 88-439, § 1, 78 Stat. 445; Oct. 21, 1976, Pub. L. 94-583, § 3, 90 Stat. 2891; Nov. 19, 1988, Pub. L. 100-702, Title II, §§ 201(a), 202(a), 203(a), 102 Stat. 4646.)

§ 1441. Actions removable generally

(a) Except as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending. For purposes of removal under this chapter, the citizenship of defendants sued under fictitious names shall be disregarded.

(b) Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States shall be removable without regard to the citizenship or residence of the parties. Any other such action shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.

(c) Whenever a separate and independent claim or cause of action within the jurisdiction conferred by section 1331 of this title, is joined with one or more otherwise non-removable claims or causes of action, the entire case may be removed and the district court may determine all issues therein, or, in its discretion, may remand all matters in which state law predominates.

(d) Any civil action brought in a State court against a foreign state as defined in section 1603(a) of this title may be removed by the foreign state to the district court of the United States for the district and division embracing the place where such action is pending. Upon removal the action shall be tried by the court without jury. Where removal is based upon this subsection, the time limitations of section 1446(b) of this chapter may be enlarged at any time for cause shown.

(e) The court to which such civil action is removed is not precluded from hearing and determining any claim in such civil action because the State court from which such civil action is removed did not have jurisdiction over that claim.

(As amended Oct. 21, 1976, Pub. L. 94-583, § 6, 90 Stat. 2898; June 19, 1986, Pub. L. 99-336, § 3(a), 100 Stat. 637; Nov. 19, 1988,

Pub. L. 100-702, Title X, § 1016(a), 102 Stat. 4669; Dec. 1, 1990, Pub. L. 101-650, Title III, § 312, 104 Stat. 5114.)

KENTUCKY STATUTES

454.210. Personal jurisdiction of courts over nonresident—Process, how served—Venue.—

(1) As used in this section, "person" includes an individual, his executor, administrator, or other personal representative, or a corporation, partnership, association, or any other legal or commercial entity, who is a nonresident of this Commonwealth.

(2)(a) A court may exercise personal jurisdiction over a person who acts directly or by an agent, as to a claim arising from the person's:

1. Transacting any business in this Commonwealth;

2. Contracting to supply services or goods in this Commonwealth;

3. Causing tortious injury by an act or omission in this Commonwealth;

4. Causing tortious injury in this Commonwealth by an act or omission outside this Commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth, provided that the tortious injury occurring in this Commonwealth arises out of the doing or soliciting of business or a persistent course of conduct or derivation of substantial revenue within the Commonwealth;

5. Causing injury in this Commonwealth to any person by breach of warranty expressly or impliedly made in the sale of goods outside this Commonwealth when the seller knew such person would use, consume, or be affected by, the goods in this Commonwealth, if he also regularly does or solicits business, or engages in any other persistent course of conduct,

or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth;

6. Having an interest in, using, or possessing real property in this Commonwealth, providing the claim arises from the interest in, use of, or possession of the real property, provided, however, that such in personam jurisdiction shall not be imposed on a nonresident who did not himself voluntarily institute the relationship, and did not knowingly perform, or fail to perform, the act or acts upon which jurisdiction is predicated;

7. Contracting to insure any person, property, or risk located within this Commonwealth at the time of contracting.

8. Committing sexual intercourse in this state which intercourse causes the birth of a child when:

a. The father or mother or both are domiciled in this state;

b. There is a repeated pattern of intercourse between the father and mother in this state; or

c. Said intercourse is a tort or a crime in this state;

(b) When jurisdiction over a person is based solely upon this section, only a claim arising from acts enumerated in this section may be asserted against him.

(3)(a) When personal jurisdiction is authorized by this section, service of process may be made on such person, or any agent of such person, in any county in this Commonwealth, where he may be found, or on the secretary of state who, for this purpose, shall be deemed to be the statutory agent of such person;

(b) The clerk of the court in which the action is brought shall issue a summons against the defendant named in the complaint. The clerk shall execute the summons by sending by certified mail two (2) true copies to the secretary of state and shall also mail with the summons two (2) attested copies of plaintiff's complaint. The secretary of state shall, within seven (7) days of receipt thereof in his office, mail a copy of the summons and complaint to the defendant at the address given in the complaint. The letter shall be posted by certified mail, return receipt requested and shall bear the return address of the secretary of state. The clerk shall make the usual return to the

court, and in addition the secretary of state shall make a return to the court showing that the acts contemplated by this statute have been performed, and shall attach to his return the registry receipt, if any. Summons shall be deemed to be served on the return of the secretary of state and the action shall proceed as provided in the Rules of Civil Procedure; and

(c) The clerk mailing the summons to the secretary of state shall mail to him, at the same time, a fee of ten dollars ($10), which shall be taxed as costs in the action.

(4) When the exercise of personal jurisdiction is authorized by this section, any action or suit may be brought in the county wherein the plaintiff resides or where the cause of action or any part thereof arose.

(5) A court of this Commonwealth may exercise jurisdiction on any other basis authorized in the Kentucky Revised Statutes or by the Rules of Civil Procedure, notwithstanding this section. (Enact. Acts 1968, ch. 46, §§ 1 to 5; 1972, ch. 307, § 3; 1974, ch. 315, § 87; 1976, ch. 27, § 20; 1978, ch. 402, § 7, effective June 17, 1978; 1980, ch. 114, § 107, effective July 15, 1980; 1982, ch. 136, § 1, effective July 15, 1982; 1982, ch. 159, § 5, effective July 15, 1982; 1984, ch. 56, § 1, effective July 13, 1984; 1986, ch. 204, § 13, effective July 15, 1986; 1988, ch. 185, § 3, effective July 15, 1988.)